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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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10/689,149

10/20/2003

Miri Seiberg

3282-P02872US04/KDR

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12/12/2011

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1601 MARKET STREET
SUITE 2400
PHILADELPHIA, PA 19103-2307

EXAMINER

PACKARD, BENJAMIN J

ART UNIT

PAPER NUMBER

1612

MAIL DATE

DELIVERY MODE

12/12/2011

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|---------------------------------------|--|
| Office Action Summary | Application No. 10/689,149 | Applicant(s) SEIBERG ET AL. | |
| | Examiner BENJAMIN PACKARD | Art Unit 1612 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 November 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 5) ☒ Claim(s) 1-32 and 34-41 is/are pending in the application.
- 5a) Of the above claim(s) 5-8, 10-12, 14-16, 21-24, 26-28 and 30-32 is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 1-4, 9, 13, 17-20, 25, 29 and 34-41 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Applicants' arguments, filed 11/30/11, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 9, 13, 17, 20, 25, 29, and 34-37 stand rejected under 35 U.S.C. 102(b) as being anticipated by Costanzo (US 6,323,219).

Applicants assert the instant claims require administration of the soybean trypsin inhibitor (STI) "prior to exposure of the skin to ultraviolet radiation", but the prior art only teaches administration after ultraviolet application, where the purpose of the prior art is to reduce pigmentation and is effective in inhibiting melanogenesis. Applicants also assert for the reference to be anticipatory, the descriptive matter must necessarily be present and that there is considerable precedent supporting the position that the claimed effect must be recognized and not an accidental or unwitting duplication. Applicants also assert the prior art teaches the use of STI to reduce melanin, but other studies had shown that melanin in dark skin reduces the amount of uv light what reaches the upper dermis and reduces the risk of skin cancer compare to Caucasian skin.

Examiner disagrees. First, Examiner notes the instant claims do not require application "prior to exposure of skin to ultraviolet radiation, but instead require application prior to skin cells that have not yet been damaged by ultraviolet radiation" (see instant claim 1). As such, the application of the STI composition to a Yucatan microswine in Example 12 appears to meet this, given there is no disclosure that the skin being tested was already uv damaged, unlike the working embodiment of Example 13, which discloses administering the agent to age spots on a patient.

Second, while Applicants cite numerous cases to support their legal position, Examiner notes that the difference between the instant case and the cited cases lies in the fact that the patient population disclosed by the prior art reference here is entirely within the claimed genus. On the other hand, the cited cases had overlapping patient populations, but lacked motivation to select a specific sub-population. As noted above, as the Yucatan microswine do not appear to have had UV exposure, but were only tested for skin depigmentation, then the patient population is entirely within the genus instantly claimed, i.e. patients without uv damaged skin. Where the same composition is administered to the same patient population, then the fact that an additional benefit has been recognized does not render the instant claims allowable. In other words, claiming a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). Here, the ability of the composition to "reduce the risk of cutaneous tumor development in skin cells" would have been met, given the same active steps are disclosed.

Finally, as noted above, regardless the teaching at the time of the invention, whether the specific mechanism of tumor development was recognized or not, the fact that the same steps were applied to the same patient population suggests the method was an inherent function, albeit an unrecognized inherent function.

Claim Rejections - 35 USC § 103

Claims 1-4, 9, 13, 17-20, 25, 29, and 34-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Costanzo (US 6,323,219).

Applicants assert the prior art does not teach administering the STI prior to exposure of the skin to ultraviolet radiation. Instead, Applicants assert based on the knowledge of the skilled artisan at the time, STI would not have been applied as it would have been thought to increase the risk of cutaneous tumor development.

Examiner disagrees. As discussed above, the embodiments disclosed appear to treat patients without uv damaged skin, thus selection of this patient population would be based on the explicit disclosure to do so.

Additionally, '219 further teaches the use of the compositions with the intent of preventing the disclosed disorders, as well as treating disorders already in progress (col 30 lines 52-60). Thus, in order to prevent skin imperfections, the skilled artisan would apply the compositions to skin which has yet to be damaged, thereby preventing the discoloration of the skin.

Conclusion

No claims allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BENJAMIN PACKARD whose telephone number is (571)270-3440. The examiner can normally be reached on M-R 8-5 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1612

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Benjamin Packard/
Primary Examiner, Art Unit 1612